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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,823	03/03/2000	JUNICHI SHIMADA	506.38266CX1	3013

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ANTONELLI TERRY STOUT AND KRAUS
SUITE 1800
1300 NORTH SEVENTEENTH STREET
ARLINGTON, VA 22209

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/486,823	Applicant(s) Shimada et al.
	Examiner Phyllis G. Spivack	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *6-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *6-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *18*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' request for a Continued Prosecution Application (CPA) filed March 4, 2003, Paper No. 19, is acknowledged. Claims 6-17 remain under consideration.

An Information Disclosure Statement filed February 19, 2002, Paper No. 18, is further acknowledged. The references have been reviewed to the extent each is in the English language.

The disclosure is objected to for the following informalities: Following a previous amendment, there are no Y_1 and Y_2 groups in claim 6.

Because Compounds 1, 2 and 3 are incorrectly represented in Table 1, on page 7 of the specification, a replacement page is requested.

Appropriate correction is required.

Claim 8 is objected to under 37 C FR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claims 6-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Although support is provided for the inhibitory activity on degeneration of dopaminergic neurons following administration of Compounds 1, 2, 3 and 4, undue experimentation would be required to practice the claimed methods.

At issue is whether or not one skilled in the neurology art could practice methods of treating various neurodegenerative disorders based on the data presented in Table 2, on page 12 of the specification and what is well known in the art. The determination of what constitutes undue experimentation in any given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.

Factors to be considered in determining whether a disclosure would require undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims.

In the instant case the state of the art is highly unpredictable with respect to conclusions dawn from laboratory data extrapolated to clinical efficacy. Accordingly, analysis of the above criteria would lead one skilled in the neurology art to the reasonable conclusion that undue experimentation would be required to practice the claimed methods of use. Particularly in view of the absence of data sufficient to support the breadth of claims directed to inhibiting neurodegeneration, and the high degree of unpredictability in the art, the specification is inadequate to support the inhibition of the many recited diverse disease states on page 13 of the specification that are encompassed by the term "neurodegeneration".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baraldi et al., Current Medicinal Chemistry.

Baraldi teaches the administration of various compounds of instant formula I in the treatment of cerebral ischemia or neurodegenerative disorders and to improve learning and enhance cognition. See Table 3, page 711. On page 13 of the specification, brain ischemia is listed among those disorders for which the present neurodegenerative methods are directed. Parkinson's disease, which is excluded from the present claims, is the only specifically recited neurodegenerative disorder disclosed by Baraldi. However, one skilled in the neurology art would have been motivated to administer 8-styrylxanthines, as disclosed by Baraldi, to treat other neurodegenerative disorders and Alzheimer's disease. Such would have been obvious in the absence of evidence to the contrary because Alzheimer's disease is characterized by a decrease in cognition. One skilled in the art would have been motivated to administer these xanthine derivatives to treat neurodegeneration based on their demonstrated potential for both anatomical and functional neuroprotection. It would have been reasonable to expect the specific adenosine receptor antagonists, as disclosed by Baraldi in Table 3, would have been effective in inhibiting neurodegeneration and treating neurodegenerative disorders, other than Parkinson's disease, in view of Baraldi's teaching.

Claims 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., EP 0 698 607.

Suzuki teaches compounds of the formulas of claims 6, 10 and 14 for use in the treatment of senile dementia. See Table 1, pages 6-8. Although senile dementia is not recited among those examples of neurodegenerative disorders disclosed in the specification, one skilled in the neurology art would have been motivated to administer a compound of instant formula I to treat Alzheimer's disease. Such would have been obvious because senile dementia, a progressive, abnormally accelerated deterioration of mental faculties and emotional stability, is a primary characterization of Alzheimer's disease.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

March 19, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER